

DMHAS OOC IRB REVIEWER CHECK LIST – Prisoner Participation

Title of Study: _____ Date of Review: _____

Reviewer: _____

| Checklist | Comment | | | |
|---|--|----------|------------|----------------|
| <p>The study represents one of the following permissible categories of research:</p> <p><input type="checkbox"/> study of the possible causes, effects, and processes of incarceration, and of criminal behavior; and the study presents no more than minimal risk and no more than inconvenience to the participants</p> <p><input type="checkbox"/> study of prisons as institutional structures or of prisoners as incarcerated persons, and the study presents no more than minimal risk and no more than inconvenience to the subjects</p> <p><input type="checkbox"/> research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research</p> <p><input type="checkbox"/> research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.</p> | <p><i>Minimal risk for prisoners is defined as:</i> the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons.</p> | | | |
| | y | n | n/a | Comment |
| <p><input type="checkbox"/> Any possible advantages that might accrue to the prisoner from participation are not of such a magnitude that the prisoner's ability to weigh the risks and benefits are impaired.</p> | | | | |
| <p><input type="checkbox"/> The risks involved in the research are commensurate with the risks that would be accepted by non-prisoners.</p> | | | | |

| | y | n | n/a | Comment |
|--|---|---|-----|---------|
| <input type="checkbox"/> Procedures for selection of prisoners are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. | | | | |
| <input type="checkbox"/> The information is presented in language understandable to the subject population. | | | | |
| <input type="checkbox"/> Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. | | | | |
| <input type="checkbox"/> Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact. | | | | |
| <input type="checkbox"/> Other | | | | |